

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
)	MDL No. 1:13-md-2419
)	
This Document Relates to:)	Judge Rya Zobel
)	
All Actions Against The Saint Thomas Entities)	
)	

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO THE
SAINT THOMAS ENTITIES' STATEMENT OF UNDISPUTED, MATERIAL
FACTS IN SUPPORT OF THEIR GLOBAL MOTION FOR PARTIAL SUMMARY
JUDGMENT ON CLAIMS FOR ACTUAL AGENCY AND DIRECT LIABILITY**

Plaintiffs’ Steering Committee responds to the Saint Thomas Entities’ Statement of Undisputed, Material Facts as follows. Throughout these responses, the entity known as Saint Thomas Outpatient Neurosurgical Center, LLC is referred to as “Saint Thomas Clinic.” The Defendants refer to that same entity as “STOPNC”.

1. **Saint Thomas Entities Statement:** Howell Allen Clinic has at all relevant times employed the persons who decided to purchase medicine from NECC, namely Dr. Culclasure (STOPNC's Medical Director) and Nurse Schamberg (STOPNC's Facilities Director). *See* February 5, 2015, Deposition of Scott Butler ("Butler I Depo."), attached as Exhibit A, at 53:2-54:8; September 17, 2015, Deposition of Scott Butler ("Butler II Depo."), attached as Exhibit B, at 16:21-24; 113:1-8. These individuals reported to Howell Allen Clinic's President and Chief Administrative Officer, respectively. *See* Exhibit B at 16:25-17:4.

PSC RESPONSE:

Plaintiffs do not dispute that Dr. Culclasure and Nurse Schamberg were employees of Howell Allen Clinic. Plaintiffs dispute that Nurse Schamberg reported to Howell Allen Clinic's Chief Administrative Officer. Nurse Schamberg specifically testified that she

reported to the medical executive committee and the governing board of Saint Thomas Clinic. (Ex. I Schamberg Dep. at 31:25-32:2).¹

Plaintiffs dispute that Dr. Culclasure reported to Howell Allen Clinic's President. According to Gregory Lanford, President of Howell Allen Clinic, and a Saint Thomas Clinic Board Member, Dr. Culclasure did not have a direct supervisor. (Ex. D Lanford Dep. at 34:8-12)

2. **Saint Thomas Entities Statement:** In 2012, Health wholly owned five hospitals and a number of physician practices and rehabilitation facilities. April 6, 2015, Deposition of Michael Schatzlein, M.D. ("Schatzlein I Depo."), attached as Exhibit C, at 21:18-22:3. Network, a wholly owned subsidiary of Health, had an ownership interest in a number of joint ventures, including STOPNC. *Id.* 22:3-22:6.

PSC RESPONSE:

Undisputed that Saint Thomas Health wholly owned five hospitals and a number of physician practices and rehabilitation facilities. However, according to Dr. Schatzlein, President and CEO of Saint Thomas Health, Saint Thomas Clinic is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep. at 21:18-22:6).

Disputed that Saint Thomas Clinic is appropriately characterized as a joint venture. According to documents produced by the defendants, the parties internally referred to Saint Thomas Clinic as a "partnership." Specifically, Gregory Lanford, M.D. (a member of the Saint Thomas Clinic board) wrote in an email to the CEO of Saint Thomas Hospital and the CEO of Saint Thomas Heath as follows:

"Our group [Howell Allen Clinic] has never considered this Joint Venture to be anything other than a partnership between Saint Thomas Hospital and Howell Allen Clinic. That's how it began and that's how it has functioned over the last 13 years. The management of the facility has shared responsibilities between our group and your hospital." (Schatzlein Dep. Ex. 160, STE_MDL_018994-018995) (emphasis added).

¹ All evidentiary citations in the PSC Responses refer to the contemporaneously filed exhibits to the Declaration of Benjamin A. Gastel. For example, Ms. Schamberg's deposition transcript and relevant exhibits to that deposition transcript are attached as Exhibit I to the Gastel Declaration. Some individuals have sat for more than one deposition, which is also why dates are listed for some deposition transcripts.

Further, Saint Thomas Health's Vice President of Corporate Responsibility Program wrote in a letter to Saint Thomas Clinic that "Saint Thomas Health **is a partner with your company** in the Saint Thomas Outpatient Clinic Center, LLC joint venture." (Ex E Butler 2/5/15 Dep. Ex. 60, STOPNC-011563)(emphasis added).

3. **Saint Thomas Entities Statement:** Health is a non-profit corporation organized under the laws of Tennessee. July 2, 2015, Deposition of Dawn Rudolph ("Rudolph II Depo."), attached as Exhibit D, at 19:15-20.

PSC RESPONSE:

Plaintiffs object to this proposed fact because it is not material to the present motion. Without waiving that objection, the fact is undisputed for the purpose of the present motion only.

4. **Saint Thomas Entities Statement:** Network and Hospital are also non-profit corporations organized under Tennessee law. *Id.* 17:19-24. Network is essentially a holding company for joint-venture investments. July 21, 2015, Deposition of Michael Schatzlein, M.D. ("Schatzlein II Depo."), attached as Exhibit E, 74:7-24; 79:5-19.

PSC RESPONSE:

Disputed as stated. The fact that Network and Hospital purport to be non-profit corporations is immaterial. Further, Dr. Schatzlein described Saint Thomas Network as a pass through entity with zero employees. (Ex. A Schatzlein 4/6/15 Dep., 32:13-20; 89:6-8).

5. **Saint Thomas Entities Statement:** STOPNC is a Tennessee limited-liability company owned 50% by Network and 50% by Howell Allen Clinic, a professional association of physicians. Exhibit A at 25:8-16; Exhibit B at 24:13-21; Exhibit E at 72:6-19. STOPNC is a joint-venture investment of Network. Exhibit C at 19:6-9; *see also* Apr. 21, 2015, Deposition of Dawn Rudolph ("Rudolph I Depo."), attached as Exhibit G, at 19:14-23.

PSC RESPONSE:

Disputed. Saint Thomas Clinic is a partnership between Saint Thomas and Howell Allen Clinic. According to documents produced by the defendants, the parties internally referred to Saint Thomas Clinic as a “partnership.” Specifically, Gregory Lanford, M.D. (a member of the Saint Thomas Clinic board) wrote in an email to the CEO of Saint Thomas Hospital and the CEO of Saint Thomas Heath as follows:

“Our group [Howell Allen Clinic] has never considered this Joint Venture to be anything other than a partnership between Saint Thomas Hospital and Howell Allen Clinic. That’s how it began and that’s how it has functioned over the last 13 years. The management of the facility has shared responsibilities between our group and your hospital.” (Ex. A Schatzlein 4/6/15 Dep. Ex. 160, STE_MDL_018994-018995) (emphasis added).

Further, Saint Thomas Health’s Vice President of Corporate Responsibility Program wrote in a letter to Saint Thomas Clinic that “Saint Thomas Health is a partner with your company in the Saint Thomas Outpatient Clinic Center, LLC joint venture.” (Ex. E Butler 2/5/15 Dep. Exhibit. 60 at STOPNC-011563). (emphasis added). Mr. Butler testified that Saint Thomas maintained an equal right, along with Howell Allen, to control Saint Thomas Clinic’s conduct. Ex E Butler 2/5/15 Dep., 31:8-24. Both members of Saint Thomas Clinic had equal control as far as the venture itself was concerned. Ex E Butler 2/5/15 Dep., 28:21-24). Moreover, it was the official policy of the Saint Thomas Clinic that “overall management of the center shall be directed by the facility administrator through the medical executive committee in conjunction with the board of directors.” (Ex F Butler 9/17/15 Dep. 44:14-25; Butler Ex. 597).

The makeup of Saint Thomas Clinic’s board of directors likewise demonstrates a system of shared control. Dale Batchelor, MD, a Saint Thomas Clinic board member and Saint Thomas Hospital’s Chief Medical Officer, testified that he and the other board members “had ultimate responsibility for the operation of” Saint Thomas Clinic. (Ex. G Batchelor Dep. 25:8-12.)

6. **Saint Thomas Entities Statement:** The parties to the Operating Agreement for STOPNC are Saint Thomas Health Services and “Neurosurgical Surgeons, P.C.” Saint Thomas Neurosurgical Center, LLC Operating Agreement (July 1, 2000) (“Operating Agreement”), attached as Exhibit F. Saint Thomas Health subsequently became Network, and the successor to Neurosurgical Surgeons, P.C. is Howell Allen Clinic. Exhibit E at 69:19-22; 76:2-9; *see also* Exhibit B at 26:6-8.

PSC RESPONSE:

Disputed as stated. Saint Thomas Health Services subsequently became Saint Thomas Network.

7. **Saint Thomas Entities Statement:** The STOPNC board has habitually observed its corporate governance requirements, holding regular board meetings and keeping corporate minutes. Exhibit B at 42:1-24. Ms. Schamberg is responsible for maintaining the minutes. *Id.* at 42:20-24.

PSC RESPONSE:

Disputed. It is further disputed that the parties observed Saint Thomas Clinic as being a separate corporate entity given that Saint Thomas Clinic printed its board reports on Saint Thomas Health letterhead, and it held its board meetings in the Saint Thomas Hospital board room. (Ex. E Butler 2/5/15 Dep., Exhibit 67; Ex. I Schamberg Dep. at 39:10-11). Further, Dale Batchelor, MD considered his role as member of Saint Thomas Clinic's governing board to be part of his job as the Chief Medical Officer of Saint Thomas Hospital. (Ex. G Batchelor Dep., 25:1-3).

Further, in his testimony, Saint Thomas Clinic board member Scott Butler testified that Saint Thomas maintained an equal right, along with Howell Allen, to control Saint Thomas Clinic's conduct. (Ex E Butler 2/5/15 Dep., 31:8-24). Both members of the joint venture had equal control as far as the venture itself was concerned. (Ex E Butler 2/5/15 Dep., 28:21-24). Further, it was the official policy of the Clinic that "overall management of the center shall be directed by the facility administrator through the medical executive committee *in conjunction with* the board of directors." (Ex. F Butler 9/17/15 Dep., 44:14-25 and Exhibit 597 at STOPNC_0607). And Dale Batchelor, MD, a Saint Thomas Clinic board member and Saint Thomas Hospital's Chief Medical Officer, testified that he and the other board members "had ultimate responsibility for the operation of" Saint Thomas Clinic. (Ex. G Batchelor Dep. 25:8-12.)

Finally, when the Saint Thomas Entities wanted to, they could and did, "essentially over[ide] the board structure of the clinic" and direct its operations. (Ex. A Schatzlein 4/6/15 Dep., 63:1-19.)

8. **Saint Thomas Entities Statement:** Under the agreement that defines their rights as owners, Howell Allen Clinic and Network each have the right to appoint two members of the

Board of Governors of STOPNC. *See* Exhibit F at § 7.2; *see also* Exhibit C at 30:16-19; Exhibit A at 28:16-24; *see also* Exhibit F at § 7.1. The Network appointments to the STOPNC Board were Craig Polkow (then-CFO of Saint Thomas Health) and Dale Batchelor, M.D. (then-Chief Medical Officer of Hospital), and for a short period, Dawn Rudolph (then-Chief Executive Officer of Hospital). Exhibit G at 21:15-25; 23:20-24:1; 80:5-8. Network's appointments to the STOPNC Board were all highly regarded professionals with significant experience in the healthcare setting. *Id.* at 17:5-14; 91:21-24; September 2, 2015, Deposition of Dale Batchelor, M.D. ("Batchelor Depo."), attached as Exhibit H at 9:15-11:1-12.

PSC RESPONSE:

Undisputed as to the first two sentences. Disputed as stated as to the last sentence. The extent to which members of Saint Thomas Clinic's board were highly regarded professionals is subjective and immaterial.

9. **Saint Thomas Entities Statement:** Pursuant to the Operating Agreement and their fiduciary duties as board members, the board of STOPNC appointed managers to run the business. Exhibit F at §§ 7.1, 8.1. It also approved a services agreement with Howell Allen Clinic to provide all of the STOPNC employees and the Medical Director. *See* Services Agreement between Neurological Surgeons, P.C. (n/k/a Howell Allen) and STOPNC ("HAC-STOPNC Services Agreement"), attached as Exhibit I; *see also* Sept. 27, 2007 Addenda to Services Agreement (STOPNC_0713-14), attached as Exhibit J (Howell Allen was to assume the "Medical Directorship," "Provide direction and leadership for the Medical Staff," "Monitor quality assurance and patient care," and "Provide all staff."); Exhibit B at 25:18-26:8; 29:22-30:22; Exhibit E at 77:1-3.

PSC RESPONSE:

Disputed. According to Dale Batchelor, MD, a Saint Thomas Clinic board member and Saint Thomas Hospital's Chief Medical Officer, Saint Thomas Clinic's board of governors had "ultimate responsibility" for the operation of Saint Thomas Clinic. (Ex. G Batchelor Dep., 25:8-12). Further, Dale Batchelor, MD considered his role as member of Saint Thomas Clinic's governing board to be part of his job as the Chief Medical Officer of Saint Thomas Hospital. (Ex. G Batchelor Dep., 25:1-3). In addition, Dr. Schatzlein, CEO of Saint Thomas Health, testified the purpose of Saint Thomas Clinic's board was to provide "oversight of management." (Ex. A Schatzlein 4/6/15 Dep., 36:20-22). Also, according to board member Scott Butler, Saint Thomas maintained an equal right, along with Howell Allen, to control Saint Thomas Clinic's conduct. (Ex. E, Butler 2/5/15 Dep. at 28:8-24).

Further disputed in that the Services Agreement cited in support of this statement flatly contradicts the facts contained in the statement and is flatly contradicted by Saint Thomas Clinic's formation documents and operating agreement. the Services Agreement allegedly supporting this statement states that "the Company [i.e. the Clinic LLC] shall at all times exercise control over the assets and operation of the Center [the Clinic]" and that "[b]y entering into this Agreement ... the Company does not delegate to the Group [Howell Allen] any of the powers, duties, and responsibilities vested in the Company by law." (Ex. F Butler 9/17/15 Dep., Exhibit 594). Further, the operative Articles of Organization of Saint Thomas Clinic state that [Saint Thomas Clinic] will be Board managed. (Ex. P Parrino Dep., Exhibit 1192). Saint Thomas Clinic's Operating Agreement gives the Saint Thomas Entities the right to unilaterally require Saint Thomas Neurosurgical, its Board, or its managers to take action or refrain from actions that could jeopardize the interests of the Saint Thomas Entities. (Ex. A Schatzlein 4/6/15 Dep., 109:17-21 and Exhibit 174 at Section 6.10.) The Operating Agreement further states that "[t]he philosophy if the LLC is that of the sponsors as articulated and promoted through the statement of mission, vision and values of Saint Thomas Health Services in accordance with the official teachings of the Roman Catholic Church and the directives." (*Id.* at Exhibit 174; *see also* Ex. Q Rudolph 4/21/15 Dep., 50:20-24; Ex. A Schatzlein 4/6/15 Dep., 117:9-19).

10. **Saint Thomas Entities Statement:** STOPNC was managed by Howell Allen Clinic pursuant to the written management agreement, and Howell-Allen employees fulfilled the roles of Medical Director and Facilities Director, charged with overseeing the day-to-day operations of STOPNC—including procurement decisions such as where to buy medication—and reporting directly to Howell Allen Clinic management. Exhibit I; *see also* Exhibit G at 101:17-24; Exhibit H at 30:17-31:14; July 15, 2015, Deposition of Rebecca Climer ("Climer II

Depo.”), attached as Exhibit K, at 75:4-20; Exhibit A at 53:2-54:8; Exhibit B at 16:25-17:4; 113:1-8. The STOPNC board members understood their role, as defined under the Operating Agreement, as being “an oversight of the . . . financial affairs of STOPNC,” while “the business and the operations of the STOPNC were under [the] management agreement” Exhibit G at 101:17-24.

PSC RESPONSE:

Disputed. According to Dale Batchelor, MD, a Saint Thomas Clinic board member and Saint Thomas Hospital’s Chief Medical Officer, Saint Thomas Clinic’s board of governors had “ultimate responsibility” for the operation of Saint Thomas Clinic. (Ex. G Batchelor Dep., 25:8-12) Further, Dale Batchelor, MD considered his role as a member of Saint Thomas Clinic’s governing board to be part of his job as the Chief Medical Officer of Saint Thomas Hospital. (Ex. G Batchelor Dep., 25:1-3). In addition, Dr. Schatzlein, CEO of Saint Thomas Health, testified that the purpose of Saint Thomas Clinic’s board was to provide “oversight of management.” (Ex A Schatzlein 4/6/15 Dep., 36:20-22). Also, according to board member Scott Butler, Saint Thomas maintained an equal right, along with Howell Allen, to control Saint Thomas Clinic’s conduct. (Ex. E Butler 2/5/15 Dep. 28:8-24).

Further disputed is that the Services Agreement contradicts the facts contained in the statement and is flatly contradicted by Saint Thomas Clinic’s formation documents and operating agreement. The Services Agreement allegedly supporting this statement states that “the Company [i.e. the Clinic LLC] shall at all times exercise control over the assets and operation of the Center [the Clinic]” and that “[b]y entering into this Agreement . . . the Company does not delegate to the Group [Howell Allen] any of the powers, duties, and responsibilities vested in the Company by law.” (Butler 9/17/15 Dep., Exhibit 594). Further, the operative Articles of Organization of Saint Thomas Clinic state that [Saint Thomas Clinic] will be Board managed. (Ex. P Parrino Dep., Exhibit 1192). Saint Thomas Clinic’s Operating Agreement gives the Saint Thomas Entities the right to unilaterally require Saint Thomas Clinic, its Board, or its managers to take action or refrain from actions that could jeopardize the interests of the Saint Thomas Entities. (Ex. A Schatzlein 4/6/15 Dep., 109:17-21 and Exhibit 174 at Section 6.10.) The Operating Agreement further states that “[t]he philosophy of the LLC is that of the sponsors as articulated and promoted through the statement of mission, vision and values of Saint Thomas Health Services in accordance with the official teachings of the Roman Catholic Church and the directives.” (*Id.* at Exhibit 174; *see also* Ex. Q Rudolph 4/21/15 Dep. 50:20-24; Ex. A Schatzlein 4/6/15 Dep., 117:9-19).

11. **Saint Thomas Entities Statement:** At the time of the meningitis outbreak in 2012, STOPNC's Medical Director was Dr. Culclasure, and its Facilities Director was Nurse Schamberg. March 23, 2015, Deposition of John W. Culclasure, M.D. ("Culclasure Depo."), attached as Exhibit L, at 14:21-23; 15:5; February 4, 2015, Deposition of Debra Schamberg, R.N. ("Schamberg Depo."), attached as Exhibit M, at 28:1-4. As Facilities Director, Nurse Schamberg oversees the day-to-day activities of STOPNC—"the staff and the running of the facility, anything that's a part of the clinical side." Exhibit M at 28:1-12.

PSC RESPONSE:

Undisputed.

12. **Saint Thomas Entities Statement:** STOPNC is located on what is known as the Saint Thomas Hospital campus. Exhibit C at 38:2-4. The medical office building in which STOPNC is located is owned by HRT, a real estate company that is not affiliated in any way with the Saint Thomas Entities. Exhibit E at 100:19-25. Howell Allen Clinic (or its predecessor) is the tenant on the STOPNC lease. Exhibit A at 166:17-167:4. Howell Allen Clinic also handles the billing for STOPNC and collects the money for patient procedures performed by STOPNC, including the epidural steroid injections ("ESIs") that contained the NECC-compounded MPA. Exhibit L at 67:4-24; 194:25-195:3.

PSC RESPONSE:

Undisputed that Saint Thomas Clinic is located on the Saint Thomas Hospital campus. Disputed as to the last sentence. Cindy Williams, Saint Thomas Health's Director of Managed Care Joint Venture Contracting facilitated the managed care contracts for Saint Thomas Clinic. Part of Ms. Williams' job responsibilities included helping Saint Thomas Clinic get paid for goods and services provided to patients. (Ex. H Williams Dep., 12:9-12; 15:15-20). Further, any profits generated by Saint Thomas Clinic, including profits derived from ESIs containing contaminated MPA, were split 50/50 between Howell Allen Clinic and Saint Thomas Network. As a pass-through entity with zero employees, half of those profits flowed to Saint Thomas Health, which also wholly owned Saint

Thomas Hospital. (Ex. A Schatzlein 4/6/15 Dep., 32:13-20; Ex. B Schatzlein 7/21/15 Dep., 60:3-7).

13. **Saint Thomas Entities Statement:** All of STOPNC's patients are referred by Howell Allen Clinic doctors. September 18, 2015, Deposition of Gregory B. Lanford, M.D. ("Lanford Depo."), attached as Exhibit N, at 68:22-69:11; Exhibit L at 153:21-22. And if the steroid injections provided by STOPNC are not successful in resolving the patient's pain, then these patients may be referred back to the Howell Allen Clinic neurosurgeons for further treatment. Exhibit C at 33:11-21.

PSC RESPONSE:

Undisputed.

14. **Saint Thomas Entities Statement:** The responsibility for purchasing medications for STOPNC patients resided solely with Nurse Schamberg in consultation with Dr. Culclasure. Exhibit B at 113:9-16. Neither Hospital nor Health nor Network has ever supplied medicines or pharmaceutical procurement services for STOPNC. Exhibit D at 69:24-70:5; August 21, 2015, Deposition of Carmen Leffler ("Leffler Depo."), attached as Exhibit O, at 105:19-106:11; 115:17-116:7; August 26, 2015, Deposition of Martin Kelvas ("Kelvas Depo."), attached as Exhibit P, at 180:9-18. STOPNC was not subject to any policies or requirements of Health or Hospital regarding medicines. Exhibit P at 65:20-66:16; 68:1-10.

PSC RESPONSE:

Disputed. The Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic) was obligated to protect the safety of patients by making sure that entities on the for-profit side of the organization followed the same rules and pharmacy procurement laws as those entities on the non-profit side of the organization. Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep., 21:18-22:6; 142:20-25). Accordingly, Saint Thomas Health, Saint Thomas Network, Saint Thomas

Hospital, and Saint Thomas Clinic, all as part of the Saint Thomas Health system, were obligated to take appropriate steps to ensure that appropriately trained personnel were in place at Saint Thomas Clinic in order to protect the safety of patients with regard to the procurement of steroids for use in ESIs. (Ex. S Declaration of James Gray, III, Pharm.D. ¶ 43).

The Saint Thomas Health system, including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic, failed to carry out those obligations. Despite the fact that the pharmacy director of Saint Thomas Hospital confirmed with the Tennessee Board of Pharmacy in early 2011 that NECC could not sell compounded drugs in Tennessee without a patient-specific prescription and communicated that information across the non-profit side of the Saint Thomas Health system, Saint Thomas Health and Saint Thomas Hospital failed to notify personnel on the for-profit side of the system - Saint Thomas Clinic - that purchasing compounded medications, in bulk and without individual prescriptions, was neither safe nor lawful. *Id.*

Patients on the for-profit side of the Saint Thomas Health system, such as those of Saint Thomas Clinic, deserve the same degree of care and safety in medication procurement as do patients on the non-profit side of the system. The failure by the Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Clinic) to make sure that medications were not purchased from compounding pharmacies, in bulk and without individual prescriptions, fell below the standard of care for a health system and was negligent and reckless. (Ex. S Declaration of James Gray, III, Pharm.D. ¶ 44).

Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep., 21:18-22:6, 142:20-25.) This meant the Clinic was required to adhere to the policies and philosophies of the Saint Thomas Entities. (Ex E Butler 2/5/15 Dep., Exhibit 60 at STOPNC-011563. In fact, Cynthia Figaro wrote to Saint Thomas Clinic and said “The STHe Corporate Responsibility Program requires that we ensure that any business associates who generate billings must have evidence of an effective compliance plan. I am requesting that you complete the enclosed questionnaire.” (*Id.*) Schatzlein himself recognized the Saint Thomas Entities’ “moral obligation” to patients of the Clinic. (Ex. Q Rudolph 4/21/15 Dep., Exhibit 233.) In fact, Schatzlein testified that one of the reasons to use the common “Saint Thomas” name across facilities was to “signal to our associates that we’re all working together for the same cause ... to motivate them around patient service, patient experience, that reaches a standard level.” (Ex. A Schatzlein 4/6/15 Dep. 51:7-51:11. Dawn Rudolph, CEO of Saint Thomas Hospital, testified that Saint Thomas expects all the health care practitioners within the system to meet the standard of care. (Ex. Q Rudolph 4/21/15 Dep. 50:21-52:7). Certainly patients would expect both the for-profit and the non-profit Saint Thomas facilities to provide the same level of patient safety and care. (Ex. L Kelvas Dep. 172:12-173:8).

Saint Thomas Health CEO Michael Schatzlein confirmed that, if Saint Thomas recognized that there was a patient safety problem at its joint venture that bears the Saint

Thomas name, they would have acted. (Ex. A Schatzlein 4/6/15 Dep., 98:5-98:21). Schatzlein would expect the Saint Thomas board members that were on the Clinic's board to address any patient safety problems that came to their attention as far as the Clinic was concerned. (Ex. A Schatzlein 4/6/15 Dep. 98:25-99:4).

15. **Saint Thomas Entities Statement:** None of the Saint Thomas Entities had any involvement with the decision of Dr. Culclasure and Nurse Schamberg to purchase MPA from NECC. Exhibit M at 237:4-9. While Hospital has its own pharmacy, it was not responsible for purchasing medications for STOPNC and has never supplied pharmaceuticals, medical supplies, or procurement services to STOPNC. Exhibit D at 69:24-70:5; Exhibit O at 105:19-106:11; 115:17-116:7; Exhibit P at 180:9-18; *see also* Exhibit M at 174:20-175:3. Hospital is a completely separate entity from STOPNC. Exhibit N at 126:13-21; *see also* Exhibit M at 30:19-20 ("Saint Thomas Hospital had nothing to do with my job . . ."). None of the Saint Thomas Entities had any involvement whatsoever in overseeing STOPNC's pharmaceutical practices, including setting policies as to what medications STOPNC would procure and provide to its patients. Exhibit C at 96:13-23; 148:17-22; Exhibit E at 40:6-10; 74:20-24; 114:15-15:11; Exhibit M at 241:7-242:5 (no familiarity whatsoever with Saint Thomas Hospital formulary).

PSC RESPONSE:

Disputed. The Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic) was obligated to protect the safety of patients by making sure that entities on the for-profit side of the organization followed the same rules and pharmacy procurement laws as those entities on the non-profit side of the organization. Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep. at 21:18-22:6, 142:20-25). Accordingly, Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Clinic, all as part of the Saint Thomas Health system, were obligated to take appropriate steps to ensure that appropriately trained personnel were in place at Saint Thomas Clinic in order to protect the safety of patients with regard to the procurement of steroids for use in ESIs. (Ex S Declaration of James Gray, III, Pharm.D. ¶ 43).

The Saint Thomas Health system, including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic, failed to carry out those obligations. Despite the fact that the pharmacy director of Saint Thomas Hospital confirmed with the Tennessee Board of Pharmacy in early 2011 that NECC could not sell compounded drugs in Tennessee without a patient-specific prescription and communicated that information across the non-profit side of the Saint Thomas Health system, Saint Thomas Health and Saint Thomas Hospital failed to notify personnel on the for-profit side of the system - Saint Thomas Clinic - that purchasing compounded medications, in bulk and without individual prescriptions, was neither safe nor lawful. *Id.*

Patients on the for-profit side of the Saint Thomas Health system, such as those of Saint Thomas Clinic, deserve the same degree of care and safety in medication procurement as do patients on the non-profit side of the system. The failure by the Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Clinic) to make sure that medications were not purchased from compounding pharmacies, in bulk and without individual prescriptions, fell below the standard of care for a health system and was negligent and reckless. (Ex S Declaration of James Gray, III, Pharm.D. ¶ 44).

16. **Saint Thomas Entities Statement:** According to STOPNC's medication errors policy, matters involving inappropriate medication use were overseen by Nurse Schamberg and reported to STOPNC's Medical Executive Committee; none of the members of that committee were employed by any of the Saint Thomas Entities. Exhibit M at 230:4-232:6.

PSC RESPONSE:

Although this fact is not material, it is undisputed for purposes of the present motion only.

17. **Saint Thomas Entities Statement:** At no point did Nurse Schamberg or Dr. Culclasure seek the advice of STOPNC's board or any board member regarding the decision to purchase medicine from NECC. Exhibit N at 56:15-23; Exhibit M at 78:13-20; *see also* Exhibit L at 120:7-121:3; Exhibit B at 113:9-16. Dr. Culclasure testified that he never consulted with any pharmacist when making the decision to start purchasing MPA from NECC. Exhibit L at

120:7-9. He stated that he did not even know who Hospital's pharmacy director was. *Id.* at 202:15-23; *see also* Exhibit M 188:17-19 (Nurse Schamberg testifying that she did not recall ever talking with the Saint Thomas Hospital pharmacy director). The Saint Thomas Entities did not know that STOPNC was purchasing from NECC prior to the outbreak. Exhibit B at 114:8-22.

PSC RESPONSE:

Undisputed that neither Nurse Schamberg nor Dr. Culclasure consulted with a pharmacist regarding the decision to purchase medicine from NECC. It is further undisputed that the Saint Thomas Entities failed to inform Saint Thomas Clinic that Saint Thomas Hospital's pharmacy director had instructed all pharmacy personnel on the non-profit side of the Saint Thomas Health system (i.e. Saint Thomas West Hospital in Nashville, Saint Thomas Midtown Hospital in Nashville, Saint Thomas Hospital for Specialty Surgery in Nashville and Saint Thomas Rutherford Hospital in Murfreesboro) not to purchase from compounding pharmacies. (Ex. L Kelvas Dep. at 109:24-111:12). However, Saint Thomas Health leadership failed to instruct anyone on the for-profit side of its organization not to buy in bulk from compounding pharmacies. (Ex. L Kelvas Dep. at 120:1-12). Patients on the for-profit side of the Saint Thomas Health system, such as those of Saint Thomas Clinic, deserve the same degree of care and safety in medication procurement as do patients on the non-profit side of the system. (Ex. S Declaration of James Gray, III, Pharm.D. ¶ 44).

Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep., 21:18-22:6, 142:20-25.) This meant the Clinic was required to adhere to the policies and philosophies of the Saint Thomas Entities. (Ex E Butler 2/5/15 Dep., Exhibit 60 at STOPNC-011563. In fact, Cynthia Figaro wrote to Saint Thomas Clinic and said "The STHe Corporate Responsibility Program requires that we ensure that any business associates who generate billings must have evidence of an effective compliance plan. I am requesting that you complete the enclosed questionnaire." (*Id.*) Schatzlein himself recognized the Saint Thomas Entities' "moral obligation" to patients of the Clinic. (Ex. Q Rudolph 4/21/15 Dep., Exhibit 233.) In fact, Schatzlein testified that one of the reasons to use the common "Saint Thomas" name across facilities was to "signal to our associates that we're all working together for the same cause ... to motivate them around patient service, patient experience, that reaches a standard level." (Ex. A Schatzlein 4/6/15 Dep. 51:7-51:11. Dawn Rudolph, CEO of Saint Thomas Hospital, testified that Saint Thomas expects all the health care practitioners within the system to meet the standard of care. (Ex. Q Rudolph 4/21/15 Dep. 50:21-52:7). Certainly patients would expect both the for-profit and the non-profit Saint Thomas facilities to provide the same level of patient safety and care. (Ex. L Kelvas Dep. 172:12-173:8).

Saint Thomas Health CEO Michael Schatzlein confirmed that, if Saint Thomas recognized that there was a patient safety problem at its joint venture that bears the Saint Thomas name, they would have acted. (Ex. A Schatzlein 4/6/15 Dep., 98:5-98:21).

Schatzlein would expect the Saint Thomas board members that were on the Clinic's board to address any patient safety problems that came to their attention as far as the Clinic was concerned. (Ex. A Schatzlein 4/6/15 Dep., 98:25-99:4).

18. **Saint Thomas Entities Statement:** The Director of Pharmacy at Hospital at the time, Marty Kelvas, testified that he never consulted with STOPNC about compounding pharmacies in general or NECC in particular and was unaware of anyone in his department having any such consultation with STOPNC. Exhibit P at 179:23-180:13; *see also* Exhibit O at 63:23-64:3; 115:5-13; 116:2-10; Exhibit G at 155:15-17. Mr. Kelvas further testified that there was a “line [] drawn in the sand,” Exhibit P at 120:1-12, between the for-profit ventures (including STOPNC) and the not-for-profit hospitals (including Hospital): “Our contracts were basically for the nonprofit side of the business. As far as any for-profit ventures, that’s a whole different class of trade. We had nothing to do with them.” Exhibit P at 65:23-66:1; *see also id.* 65:6-66:17 & 68:1-10 (context for the answer). The decision by Nurse Schamberg and Dr. Culclasure to purchase NECC-compounded MPA was never brought to the attention of the STOPNC board before the meningitis outbreak. Exhibit B at 113:23-114:7. In fact, there is no evidence that any of the STOPNC board members appointed by Network—or any other employee of the Saint Thomas Entities—was aware that STOPNC was purchasing products from a compounding pharmacy, including NECC. *Id.* at 114:18-22.

PSC RESPONSE:

Undisputed. However, the Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic) was obligated to protect the safety of patients by making sure that entities on the for-profit side of the organization followed the same rules and pharmacy procurement laws as those entities on the non-profit side of the organization. Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep. at 21:18-22:6, 142:20-25). Accordingly, Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Clinic, all as part of the Saint Thomas Health system, were

obligated to take appropriate steps to ensure that appropriately trained personnel were in place at Saint Thomas Clinic in order to protect the safety of patients with regard to the procurement of steroids for use in ESIs. (Ex S Declaration of James Gray, III, Pharm.D. ¶ 43).

The Saint Thomas Health system, including Saint Thomas Health, Saint Thomas Hospital, Saint Thomas Network, and Saint Thomas Clinic, failed to carry out those obligations. Despite the fact that the pharmacy director of Saint Thomas Hospital confirmed with the Tennessee Board of Pharmacy in early 2011 that NECC could not sell compounded drugs in Tennessee without a patient-specific prescription and communicated that information across the non-profit side of the Saint Thomas Health system, Saint Thomas Health and Saint Thomas Hospital failed to notify personnel on the for-profit side of the system - Saint Thomas Clinic - that purchasing compounded medications, in bulk and without individual prescriptions, was neither safe nor lawful. *Id.*

Patients on the for-profit side of the Saint Thomas Health system, such as those of Saint Thomas Clinic, deserve the same degree of care and safety in medication procurement as do patients on the non-profit side of the system. The failure by the Saint Thomas Health system (including Saint Thomas Health, Saint Thomas Network, Saint Thomas Hospital, and Saint Thomas Clinic) to make sure that medications were not purchased from compounding pharmacies, in bulk and without individual prescriptions, fell below the standard of care for a health system and was negligent and reckless. (Ex. S Declaration of James Gray, III, Pharm.D. ¶ 44).

Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep., 21:18-22:6, 142:20-25.) This meant the Clinic was required to adhere to the policies and philosophies of the Saint Thomas Entities. (Ex E Butler 2/5/15 Dep., Exhibit 60 at STOPNC-011563. In fact, Cynthia Figaro wrote to Saint Thomas Clinic and said “The STHe Corporate Responsibility Program requires that we ensure that any business associates who generate billings must have evidence of an effective compliance plan. I am requesting that you complete the enclosed questionnaire.” (*Id.*) Schatzlein himself recognized the Saint Thomas Entities’ “moral obligation” to patients of the Clinic. (Ex. Q Rudolph 4/21/15 Dep., Exhibit 233.) In fact, Schatzlein testified that one of the reasons to use the common “Saint Thomas” name across facilities was to “signal to our associates that we’re all working together for the same cause ... to motivate them around patient service, patient experience, that reaches a standard level.” (Ex. A Schatzlein 4/6/15 Dep. 51:7-51:11. Dawn Rudolph, CEO of Saint Thomas Hospital, testified that Saint Thomas expects all the health care practitioners within the system to meet the standard of care. (Ex Q Rudolph 4/21/15 Dep. 50:21-52:7). Certainly patients would expect both the for-profit and the non-profit Saint Thomas facilities to provide the same level of patient safety and care. (Ex. L Kelvas Dep. 172:12-173:8).

Saint Thomas Health CEO Michael Schatzlein confirmed that, if Saint Thomas recognized that there was a patient safety problem at its joint venture that bears the Saint Thomas name, they would have acted. (Ex. A Schatzlein 4/6/15 Dep., 98:5-98:21).

Schatzlein would expect the Saint Thomas board members that were on the Clinic's board to address any patient safety problems that came to their attention as far as the Clinic was concerned. (Ex. A Schatzlein 4/6/15 Dep. 98:25-99:4).

19. **Saint Thomas Entities Statement:** It is the corporate policy of Health to have written agreements for service arrangements between its affiliates and other entities. Exhibit C at 95:15-19. Health has a single- services agreement with STOPNC through which it provided non-exclusive assistance with managed-care contracts in exchange for \$3,500/year. Services Agreement (Jan. 1, 2004) ("Managed Care Services Agreement"), attached as Exhibit Q; Exhibit E at 98:17-23; 99:12-23. That is the only agreement between those two parties, and there is no evidence of any other involvement by Health in the daily operations of STOPNC. Exhibit E at 49:16-20; 58:15-18; 70:12-14; *id.* at 123:24 (Health's CEO, when asked why he had never been to the STOPNC facility: "We don't own or operate [STOPNC]"); *see also* Exhibit G at 101:21-24.

PSC RESPONSE:

Disputed. There is evidence of Health's involvement in the daily operations of Saint Thomas Clinic. Specifically, Saint Thomas Clinic printed its board reports on Saint Thomas Health letterhead, and it held its board meetings in the Saint Thomas Hospital board room. (Ex. E Butler 2/5/15 Dep., Exhibit 67; Ex. I Schamberg Dep. at 39:10-11). Saint Thomas Health's Vice President of Corporate Responsibility Program wrote in a letter to Saint Thomas Clinic that "Saint Thomas Health is a partner with your company in the Saint Thomas Outpatient Clinic Center, LLC joint venture." (Ex E Butler Dep., Exhibit 60 at STOPNC-011563). Further, as soon as Saint Thomas Health learned about the burgeoning fungal meningitis outbreak, Saint Thomas Health, through its marketing department, assumed control of Saint Thomas Clinic's communications with patients. In fact, Saint Thomas Health's Chief Marketing Officer prepared a written script that Saint Thomas Clinic used during telephone calls to patients inquiring about possible meningitis symptoms. (Ex. C Climer 4/8/15 Dep. at 25:7-24). In addition, Dr. Schatzlein testified that Saint Thomas Clinic is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep. at 21:18-22:6, 142:20-25).

Dr. Schatzlein, President and CEO of Saint Thomas Health, testified that Saint Thomas Clinic is a for-profit joint venture which is part of the Saint Thomas Health system. (Ex. A Schatzlein 4/6/15 Dep., 21:18-22:6, 142:20-25.) This meant the Clinic was required to

adhere to the policies and philosophies of the Saint Thomas Entities. (Ex E Butler 2/5/15 Dep., Exhibit 60 at STOPNC-011563. In fact, Cynthia Figaro wrote to Saint Thomas Clinic and said “The STHe Corporate Responsibility Program requires that we ensure that any business associates who generate billings must have evidence of an effective compliance plan. I am requesting that you complete the enclosed questionnaire.” (*Id.*) Schatzlein himself recognized the Saint Thomas Entities’ “moral obligation” to patients of the Clinic. (Ex. Q Rudolph 4/21/15 Dep., Exhibit 233.) In fact, Schatzlein testified that one of the reasons to use the common “Saint Thomas” name across facilities was to “signal to our associates that we’re all working together for the same cause ... to motivate them around patient service, patient experience, that reaches a standard level.” (Ex. A Schatzlein 4/6/15 Dep. 51:7-51:11. Dawn Rudolph, CEO of Saint Thomas Hospital, testified that Saint Thomas expects all the health care practitioners within the system to meet the standard of care. (Ex. Q Rudolph 4/21/15 Dep. 50:21-52:7). Certainly patients would expect both the for-profit and the non-profit Saint Thomas facilities to provide the same level of patient safety and care. (Ex. L Kelvas Dep. 172:12-173:8).

Saint Thomas Health CEO Michael Schatzlein confirmed that, if Saint Thomas recognized that there was a patient safety problem at its joint venture that bears the Saint Thomas name, they would have acted. (Ex. A Schatzlein 4/6/15 Dep., 98:5-98:21). Schatzlein would expect the Saint Thomas board members that were on the Clinic’s board to address any patient safety problems that came to their attention as far as the Clinic was concerned. (Ex. A Schatzlein 4/6/15 Dep. 98:25-99:4).

Additionally, Gregory Lanford, M.D. (a member of the Saint Thomas Clinic board) wrote in an email to the CEO of Saint Thomas Hospital and the CEO of Saint Thomas Heath as follows:

“Our group [Howell Allen Clinic] has never considered this Joint Venture to be anything other than a partnership between Saint Thomas Hospital and Howell Allen Clinic. That’s how it began and that’s how it has functioned over the last 13 years. The management of the facility has shared responsibilities between our group and your hospital.” (Ex. A Schatzlein 4/6/15 Dep., Exhibit 160 at STE_MDL_018994-018995) (emphasis added).

Further disputed in that the Services Agreement contradicts the facts contained in the statement and is flatly contradicted by Saint Thomas Clinic’s formation documents and operating agreement. the Services Agreement allegedly supporting this statement states that “the Company [i.e. the Clinic LLC] shall at all times exercise control over the assets and operation of the Center [the Clinic]” and that “[b]y entering into this Agreement ... the Company does not delegate to the Group [Howell Allen] any of the powers, duties, and responsibilities vested in the Company by law.” (Ex. E Butler 9/17/15 Dep., Exhibit 594). Further, the operative Articles of Organization of Saint Thomas Clinic state that [Saint Thomas Clinic] will be Board managed. (Ex. P Parrino Dep., Exhibit 1192). Saint Thomas Clinic’s Operating Agreement gives the Saint Thomas Entities the right to unilaterally require Saint Thomas Neurosurigcal, its Board, or its managers to take action or refrain from actions that could jeopardize the interests of the Saint Thomas Entities.

(Ex. A Schatzlein 4/6/15 Dep., 109:17-21 and Exhibit 174 at Section 6.10.) The Operating Agreement further states that “[t]he philosophy if the LLC is that of the sponsors as articulated and promoted through the statement of mission, vision and values of Saint Thomas Health Services in accordance with the official teachings of the Roman Catholic Church and the directives.” (*Id.* at Exhibit 174; *see also* Ex. Q Rudolph 4/21/15 Dep. 50:20-24; Ex. A Schatzlein 4/6/15 Dep., 117:9-19).

Further disputed in that there have been numerous instances where Saint Thomas Entities have been involved in the day-to-day operations of Saint Thomas Clinic. For example, In 2008, Saint Thomas Health Chief Marketing Officer Rebecca Climer assisted with public relations at Saint Thomas Clinic by suggesting to Saint Thomas Entities’ public relations firm Jarrard, Inc. that “We may want to feature the docs at STOPNC for pain management” in certain healthcare trade publications. (Ex. C Climer 4/8/15 Dep. 32:1-32:22 and Exhibit 182 at STE_MDL_005887.) In 2011, the Saint Thomas Entities considered sponsoring a seminar about pain management featuring the Saint Thomas Clinic that would “emphasize each aspect of the continuum of care and our services within that area” and “messaging can be in the form of cross-selling, onsite seminars, outreach seminars, etc.” (Ex. C Climer 4/8/15 Dep. 36:7-36:12 and MDL Ex. 183 at STE_MDL_023197.) Moreover, as soon as Saint Thomas Health learned about the burgeoning fungal meningitis catastrophe, Saint Thomas Health, through its marketing department, assumed control of Saint Thomas Clinic’s communications with patients. (Ex. D Lanford 9/18/15 Dep. 114:7-114:16). Executives from Saint Thomas Health and Saint Thomas Hospital – including some who were not Clinic board members – acted as the decision-makers regarding Saint Thomas Clinic’s actions and communications during the catastrophe. (Ex. D Lanford 9/18/15 Dep. 114:7-114:16). Scott Butler (of Howell Allen) testified that he did not have any control over Saint Thomas Clinic’s public relations related to the catastrophe. (Ex E Butler 2/5/15 Dep. 35:5-35:13 and 60). The Saint Thomas Entities’ executives, communications chief, and lawyers took control of all public relations and communications for the Clinic after the catastrophe. (Ex. C Climer 4/5/15 Dep., Exhibit 204).

According to Dr. Schatzlein (CEO of Saint Thomas Health), he “essentially overrode the board structure of the clinic” in order to give Rebecca Climer (Chief Marketing Officer for Saint Thomas Health) authority to direct the Clinic’s communications with patients. Executives and lawyers for Saint Thomas Health then created a written script used by the Clinic when it called patients to inquire about meningitis symptoms. (Ex. A Schatzlein 4/6/15 Dep. 63:1-63:19; Ex. C Climer 4/8/15 Dep. at 25:7-25:24.) For example, Berry Holt, attorney for Saint Thomas Hospital and Saint Thomas Health, reviewed and edited a written script that the Clinic then used when calling patients in order to inquire about potential meningitis symptoms. (Ex E Butler 2/5/15 Dep. 110:3-110:24; Ex. A Schatzlein 4/6/15 Dep. 63:23-64:11; and Exhibit 166 at STOPNC-0003501.)

In addition to controlling the Clinic’s communications with patients, the Saint Thomas Entities likewise controlled its post-catastrophe public relations. In other words, language for a post-outbreak press release by the Clinic was created by Saint Thomas Health’s Chief Marketing Officer, and reviewed and approved by the Clinic board, the CEO of Saint Thomas Hospital, and the Saint Thomas Entities’ lawyers. (Ex. Q Rudolph

4/21/15 Dep. 223:21-224:16.) At no point did Howell Allen or the Saint Thomas Clinic pay any money to Saint Thomas Health or Saint Thomas Hospital for their handling of those public relations efforts. (Ex. D Lanford 9/18/15 Dep. 114:7-114:16.)

20. **Saint Thomas Entities Statement:** Hospital also has a written agreement to provide certain fee-based services—accounting, food services, and instrument sterilization—to STOPNC, all of which are defined in an agreement. Services Agreement (Sept. 18, 2000), attached as Exhibit R; *see also* Exhibit E at 102:5-107:4; 109:23-110:24; 111:20-112:21.

PSC RESPONSE:

Disputed that those are the only services provided by Saint Thomas Hospital to Saint Thomas Clinic. Specifically, Saint Thomas Hospital's infection control nurse, Candace Smith was the first person to communicate with Saint Thomas Clinic about a potential problem with contaminated medications. Nurse Smith previously helped Saint Thomas Clinic with some of its infection control measures. Nurse Schamberg (of Saint Thomas Clinic) would occasionally call Nurse Smith (of Saint Thomas Hospital) when she had questions regarding infection control. Neither Nurse Smith nor Saint Thomas Hospital billed for those consultations. (Ex. I Schamberg Dep. at 188:22 – 189:11; 191:10-19). In addition, Saint Thomas Hospital assumed control of treating many of the patients who became ill after receiving contaminated injections at Saint Thomas Clinic. (Ex. T Latham Dep. at 23:24-24:3). Finally, Gregory Lanford, M.D. (a member of the Saint Thomas Clinic board) wrote in an email to the CEO of Saint Thomas Hospital and the CEO of Saint Thomas Heath as follows:

“Our group [Howell Allen Clinic] has never considered this Joint Venture to be anything other than a partnership between Saint Thomas Hospital and Howell Allen Clinic. That's how it began and that's how it has functioned over the last 13 years. The management of the facility has shared responsibilities between our group and your hospital.” (Ex. A Schatzlein 4/6/15 Dep., Exhibit 160 at STE_MDL_018994-018995) (emphasis added).

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Further, the operative Articles of Organization of Saint Thomas Clinic state that [Saint Thomas Clinic] will be Board managed. (Ex. P Parrino Dep., Exhibit 1192). Saint Thomas Clinic's Operating Agreement gives the Saint Thomas Entities the right to unilaterally require Saint Thomas Neurosurgical, its Board, or its managers to take action or refrain from actions that could jeopardize the interests of the Saint Thomas Entities. (Ex. A Schatzlein 4/6/15 Dep., 109:17-21 and Exhibit 174 at Section 6.10.) The Operating Agreement further states that "[t]he philosophy if the LLC is that of the sponsors as articulated and promoted through the statement of mission, vision and values of Saint Thomas Health Services in accordance with the official teachings of the Roman Catholic Church and the directives." (*Id.* at Exhibit 174; *see also* Ex. Q Rudolph 4/21/15 Dep. 50:20-24; Ex. A Schatzlein 4/6/15 Dep., 117:9-19).

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21. **Saint Thomas Entities Statement:** Plaintiffs have attempted to provide additional specifics in their contention interrogatory responses, but have not amended the complaints that contain the direct-liability allegations. *See, e.g., Plaintiffs' Second Supplemental Response to Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; and Debra V. Schamberg, R.N., First Interrogatories and Requests for Production of Documents Propounded to the Plaintiffs* (Sept. 29, 2015), attached as Exhibit S, First Supplemental Answer to Interrogatory 13.

PSC RESPONSE:

Disputed. This statement calls for a legal conclusion.

Date: April 20, 2016

Respectfully Submitted:

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: April 20, 2016

/s/ Benjamin A. Gastel
Benjamin A. Gastel